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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,703	02/25/2002	Roberto Furia	8240-11	5318

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EXAMINER	
JAWORSKI, FRANCIS J	
ART UNIT	**PAPER NUMBER**
3737	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,703	FURIA, ROBERTO	
	Examiner	Art Unit	
	Jaworski Francis J.	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-96* is/are pending in the application.

4a) Of the above claim(s) *18-36 and 46-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,37-43 and 45* is/are rejected.

7)☒ Claim(s) *44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 – 17 and 37 – 45 are present for examination in this case ; claims 18 – 36 and 46 – 96 are withdrawn from consideration pursuant to the election made in paper No. 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 14, 37-39, 43 and 45 are rejected under 35 U.S.C. 103(a) as being obvious over Stedman et al (US4883059) in view of Kopp et al(US4108165)..

With respect to claim 1, Stedman et al teaches a needle guide device 10 for an ultrasound probe 12 which device includes a base body 34 having means 22, 24 for attaching to the probe and an elongated guide hole for a needle 13, the guide 10 being made of two removably connectable parts in the form of base 34 with slot 26 defined by shoulders 36 and cover 30 removable via curved lips 32 such that cover 30 together with slot 26 form complementary parts of a delimiting wall of the guide hole (see Fig. 7

end view) which when connected form a 360 degree covering wall over substantially the entire guide hole length. It would have been obvious in view of Kopp et al to form the guide from generally symmetrical wall elements since from col. 3 lines 8-27 it was known to modify such a guidewall to be of complementary mating parts either alone or via an inner conforming lines since this overall conforms more closely to the cross-section of the needle and improves its confinement.

With respect to claim 2, the slot 26 defined by shoulder ramps 34 and the cover 30 contact at what amounts to a secant location on the hole perimeter, and the bottom of the cover 30 i.e. the base of its convexity is characterizable as the base of a groove such that the guide is characterizable as formed by a plurality of grooves.

With respect to claim 3 the separation plane is necessarily parallel to the guide hole axis as disclosed since 30 forms a continual lid or apposed covering for the groove 26 which defines this axis.

With respect to claim 4, while it is clear what applicant means, namely that the guide hole is for example not chamfered over its entire length and therefore forms a close guide hole perimeter mating to the needle surface, no particular needle size or cross-sectional shape is recited and therefore Fig. 7 shows such a feature of a uniform cross-section over the guide length.

With respect to claim 14, shoulders 36 acting together with lips 32 would act to center cover 30 over the base of the guide as well as interlock it therewith.

With respect to claims 37-39, the Stedman et al probe12 includes an ultrasound scanhead with rounded tip 14 and an endo-cavitrary intra-vaginal tapered

body 16 on which the needle guide rests at a few partial end portions 22, 24 along its own tapered length as per Fig. 2 . Hence the combination of needle guide and probe is also anticipated, in consideration with the device locking and wall delineation features as discussed above for example wrt claim 1.

With respect to claim 43, forward attachment collar 22 is characterizable as an engagement means for holding the needle guide base against the probe, and the guide is removably secured by rear clamp collar 24.

With respect to claim 45, since the claim recites 'at least one elongated guide hole', in the singular case of only one such hole and needle the end-portion claim recitation of 'any other needles passing through guide holes...' becomes non-limiting and Stedman et al col. 1 lines lines 4-30 announcing in effect that the invention is in the field of devices wherein the needle extending from the guide is viewable by the ultrasound scan suffices to anticipate this aiming feature.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 , 4, 8, 10, 15, 40-42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stedman et al in view of Kopp et al as argued against claim 1 supra, further in view of Wung et al (US5623931).

With respect to claims 2 and 10, and in the sense that Stedman et al be argued not to contain a groove in cover 30 as opposed to a general concavity and/or that Stedman et al not meet the alternative that the guidehole be of two complementary grooved parts as opposed to a single groove and a lid cover 30, it would have nonetheless been obvious in view of Wung et al 130 and 150 of Figs. 4 and 5 to form guide grooves in Stedman et al of true complementary groove sets dimensioned to a circular needle since this allows a positive tight fit (conforms more exactly to a circular needle diameter) and also allows for more complicated groove patterns such as multiple angulations to be contrived.

With respect to claim 4 and in the sense that the claim be construed as referring to a conventional needle of circular cross-section, and whereas the cover-and-groove arrangement of Stedman et al while not e.g. chamfered soas to deliberately not closely fit *any* needle regardless of cross-section be none-the-less considered to be not per se capable of closely adhering to such a circular cross-section needle by virtue of groove 26 and lid 30 having differing curvature radii, then it would have been none-the-less obvious in view of Wung et al to make grooves 610-630 and 710-730 of identical cross-sectional curvature radius such that when the guide-hole halves are assembled a conventional needle of matched diameter would be tightly apposed or adhered to.

With respect to claim 8, whereas Stedman et al does not teach use of more than a two-part guide, it would have been obvious in view of Wung et al to include in the portion of the device providing the delimiting walls an additional third part 120 soas to lock the delimiting walls together and with respect to the base body 110 for the advantage that fewer parts need be disposable versus re-sterilizable..

With respect to claim 15, Stedman et al is silent as to the needle guide wall-forming parts having a removable mutual locking means. However it would have been obvious in view of Wung et al element 120 of Figs. 1 and 3 to provide such a mutual locking means since this allows for formation of the guide walls to be independently removable with respect to the device remainder.

With respect to claims 40-41, whereas Stedman et al do not per se use detent-type attachment of the needle guide device to the body of the ultrasound probe, it would have been obvious in view of Wung et al Fig. 2 elements 2`10, 220, 230 and Fig. 6 280, 290, 300 and col. 2 lines 28 – 49 to do so since this would eliminate the risk of loss of centering about the probe circumference in Stedman et al. The use of end-portion attachment points 22, 24 is otherwise directly shown in Stedman et al.

With respect to claim 42, the forward engagement extension 22 when formed using the modification of Wung et al would engage on the side facing the probe case and function without a substantial step or discontinuity in view of the slender profile shown in fig. 1.

With respect to claim 45 as this claim is understood to pertain to a multiple needle guide alternative, although Stedman et al col. 2 line 20 as noted above as well

as Wung et al col. 1 lines 14 – 15 teach use of the needle guide soas to angulate the needle into the ultrasound view field, Stedman et al does not teach the multiple needle guide angulation case, however it would have been obvious in view of Wung et al 610 - 630, 710 – 730 to do so ssince this allows flexibility of approach to the in situ worksite in the presence of intervening structures.

Claims 5 – 7, 9, 11-13, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stedman et al in view of Kopp et al as applied to claim 1 above, and further in view of Miller et al (US5758650 of record).

With respect to claim 5, Stedman et al does not teach a polygonal cross-section e.g. for groove 26. However it would have been obvious in view of Miller et al Fig. 7 element 600 to provide same since as stated in col. 7 lines 8 – 27 this provides a positive fixed angle trajectory for needle aiming while minimizing friction between the needle and its guide by virtue of confining contact only at the needle surface tangent when a conventional needle is used.

With respect to claim 6, whereas Stedman et al does not teach a separation surface between 30 and 26 having a broken rectangular profile, given that it would have been obvious to have a polygonal separation surface profile as argued against claim 5, it would have been further obvious to provide a rectangular ribbed surface since Miller et al in col. 7 line 23 notes that a rectangular groove variant is an alternative, whereupon the shoulders of at least one such formed groove would then parallel ribs.

With respect to claim 7, whereas Stedman et al does not teach the feature, plural such grooves of parallel broken rectangle pairs would be substitutable in view of Miller et al , see900A-C of Fig. 9, and/or such grooves may be all parallel, see col. 7 lines 62 – 64 since this evokes line needle contact along the device length to minimize friction.

With respect to claim 9, Stedman et al teachs use of an abutment or support surface 36 on the needle guide base of Fig. 2 for support via 32 of the second part of the needle guide 30, and teaches use of 30 as an effective wall or lid/cover for the needle 13, however it does not teach a specific longitudinal groove therein since the groove is found within the base. It would have been obvious however in view of Miller et al to modify Stedman et al to form a groove 600 in a lid cap 116 since Miller et al notes in col. 7 lines 28 – 32 that when one does so this allows to accommodate different needle sizes via maintaining a size selection of this cheapest component of the assembly.

With respect to claim 11, since in Miller et al the longitudinal grooves may be found in either the base main body or the cap, when found in the main body the bottom and side walls for a rectangular groove as discussed re claim 6 supra would then be found in the base and appose to a delimiting wall formed by the needle guide second part.

With respect to claim 12 the aforementioned language 'may be..' is only inferential of a structural alternative such that the claim 11 rejection carries forward.

With respect to claim 13, in the parallel groove case mentioned above regarding claim 7 would result in alternate and complementary grooves in the rectangular groove profile suggested in Miller et al.

With respect to claims 16-17, in Stedman et al thumbscrew 44 brings flanges 46 together, in Miller et al thumbscrew 230 may be used to close clamping jaws 220, 222. Therefore the use of thumbscrews to clamp or incompletely clamp biopsy guide device portions together alternative to separable lips 32 in Stedman et al would have been well-known.

Allowable Subject Matter

Claim 44 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment Arguments

Applicant's arguments regarding general symmetry of mating guide wall components is not considered to be persuasive since it was known in the art to provide same by the conforming surfaces of the guidewall-forming components. Whereas Kopp et al is not a relatively long guide in terms of the insertable biopsy needle with which it is used, applicant recites that the guide is conformingment arguments are narrower in scope than the claim language.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

05272005

Francis J. Jaworski
Primary Examiner